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ERIC J. BECKMAN ET AL.

AUG 15 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

ERIC J. BECKMAN et al.

Serial No.: 10/759,904

Filed: JANUARY 16, 2004

Art Unit: 1618

Examiner: James William Rogers

Attorney Docket No.: 02-012

BIODEGRADABLE POLYURETHANES  
AND USE THEREOFPittsburgh, Pennsylvania 15230  
August 15, 2006Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## CERTIFICATE OF TRANSMISSION BY FAX

I hereby certify that this Response and the accompanying papers  
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On August 15, 2006  
Date

/Henry E. Bartony, Jr., Reg. No. 34,772/

Henry E. Bartony Jr.  
Registration No. 34,772

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

This Response to Restriction Requirement ("Response") is in response to the Office Action dated May 17, 2006. A petition for extension and authorization to charge the associated fee accompanies this Response, thereby extending the period for response up to and including August 16, 2006.

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In the Office Action dated May 17, 2006 the Examiner required restriction to one of the following asserted inventions 35 U.S.C. Section 121:

- I. Claims 1-39, drawn to a biodegradable and biocompatible polyurethane composition, classified in class 424, subclass 78.27.
- II. Claims 40-58, drawn to a method of synthesizing a bone tissue engineering scaffold, classified in class 424, subclass 549.
- III. Claims 59-68, drawn to a method of delivering a bioactive agent into an organism, classified in class 604, subclass 21.
- IV. Claim 69, drawn to an implant for insertion into an organism, classified in class 424, subclass 423.
- V. Claims 70-97, drawn to a biodegradable polyurethane composition comprising hard and soft segments, classified in class 424, subclass 78.17.
- VI. Claim 98, drawn to a composition having the formula drawn in claim, classified in class 522, subclass 97.
- VII. Claim 99, drawn to a composition having the formula drawn in claim, classified in class 564, subclass 414.
- VIII. Claims 100 and 102, drawn to a composition having the formula drawn in claim, classified in class 524, subclass 601.
- IX. Claim 101 and 103, drawn to a composition having the formula drawn in claim, classified in class 514, subclass 143.

Specifically, the Examiner asserted that:

Inventions I, II, III, IV, VI, VII, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have a different mode of operation, design and effect. For instance Invention I is drawn to a biocompatible polyurethane composition while invention II is drawn to a method of synthesizing a bone tissue comprised of human osteoblastic precursor cells, invention III is drawn to a method of delivering a bioactive agent comprised of injecting at least one multifunctional isocyanate and at least one bioactive agent into the organism, invention IV is drawn to an implant for insertion into an organism, the implant being formed external to the organism and inventions VI-IX are claims directed to compositions each claiming a different compound.

Inventions II, III, IV, V, VI, VII, VIII and IX are unrelated. Inventions are unrelated

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if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have a different mode of operation, design and effect. For instance invention II is drawn to a method of synthesizing a bone tissue comprised of human osteoblastic precursor cells, invention III is drawn to a method of delivering a bioactive agent comprised of injecting at least one multifunctional isocyanate and at least one bioactive agent into the organism, invention IV is drawn to an implant for insertion into an organism, the implant being formed external to the organism, invention V is drawn to a biodegradable polyurethane composition comprising hard and soft segments and inventions VI-IX are claims directed to compositions each claiming a different compound.

Inventions I and V are related as products which share an disclosed common utility linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are NOT required to perform the common utility or (2) that the products as claimed encompass embodiments that are NOT required to have the substantial structural feature. In this case, invention V requires a hard and soft segment not required in invention I therefore the two polymeric compositions do not share the same substantial structural feature.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: 1) The various multifunctional isocyanate precursors in claims 12-14, 50-54 2) The type of chain extenders in claims 17-18, 31, 34, 39, 41, 45, 58, 62, 66 3) The various bioactive agents in claim 48-49 4) The type of injections in claims 63, 65, 68 5) The various chain extenders in the hard segment in claims 70, 73-74, 76-86, 88, 91-91.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims are generic. Note: the elected species will name a specific multifunctional isocyanate precursor, chain extender, bioactive agent, type of injection and a specific chain extender in the hard segment.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of

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claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants hereby elect Claims 1-39 of Group I set forth by the Examiner with traverse.

In that regard, Applicants respectfully request that claim 69 of Group IV be examined with claims 1-39 of Group I. In that regard, claims 1-39 are drawn to a biodegradable and biocompatible polyurethane composition and a method synthesizing that composition. Claim 69 is drawn to an implant for insertion into an organism formed of the composition of claim 1. Applicants respectfully assert that examination of the claims of Groups I and IV will require search of essentially the same art and will not place an undue burden upon the Examiner. In the interest of expedient and efficient prosecution, Applicants respectfully request that the claims of Groups I and IV be examined together. —

With respect to the species or type of multifunctional isocyanate precursors set forth in claims 12-14, applicants elect the species wherein the multifunctional isocyanate precursor is an aliphatic multifunctional isocyanate, which reads on claims 12.

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With respect to the species or type of chain extender as set forth in claims 17, 18, 31, 34 and 39, applicants elect the species wherein the chain extender is water, which reads on claims 18, 31, 34 and 39.

Applicants respectfully requests that the Examiner indicate the allowability of Claims 1-39 and 69 and arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,  
ERIC J. BECKMAN et al.

Date: August 15, 2006

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